

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

**ALLIANCE FOR HIPPOCRATIC
MEDICINE**, on behalf of itself, its member
organizations, their members, and their
members' patients; **AMERICAN
ASSOCIATION OF PRO-LIFE
OBSTETRICIANS AND
GYNECOLOGISTS**, on behalf of itself, its
members, and their patients; **AMERICAN
COLLEGE OF PEDIATRICIANS**, on
behalf of itself, its members, and their
patients; **CHRISTIAN MEDICAL &
DENTAL ASSOCIATIONS**, on behalf of
itself, its members, and their patients;
SHAUN JESTER, D.O., on behalf of
himself and his patients; **REGINA FROST-
CLARK, M.D.**, on behalf of herself and her
patients; **TYLER JOHNSON, D.O.**, on
behalf of himself and his patients; and
GEORGE DELGADO, M.D., on behalf of
himself and his patients,
Plaintiffs,

v.

**U.S. FOOD AND DRUG
ADMINISTRATION**;
ROBERT M. CALIFF, M.D., in his official
capacity as Commissioner of Food and
Drugs, U.S. Food and Drug Administration;
PATRIZIA CAVAZZONI, M.D., in her
official capacity as Director, Center for Drug
Evaluation and Research, U.S. Food and
Drug Administration; **U.S. DEPARTMENT
OF HEALTH AND HUMAN SERVICES**;
and **XAVIER BECERRA**, in his official
capacity as Secretary, U.S. Department of
Health and Human Services,
Defendants.

Case No. 2:22-cv-00223-Z

ORDER GRANTING PRELIMINARY INJUNCTION

Before the Court is Plaintiffs' Motion for Preliminary Injunction. After due consideration of the briefing and arguments, the complaint and its attachments, the evidence presented, and applicable law, the Court holds that Plaintiffs have shown a substantial likelihood of success on the merits, a substantial threat of irreparable harm if an injunction does not issue, that the threatened injury outweighs any harm that will result if the injunction is granted, and that the grant of an injunction is in the public interest.

It is therefore ORDERED that Plaintiffs' Motion for Preliminary Injunction [ECF No. ____] is GRANTED as to all Defendants.

It is FURTHER ORDERED that, for the period of time while this lawsuit is pending or until the court otherwise amends this order, Defendants are ordered to:

- 1) Withdraw or suspend its September 28, 2000, Approval of Mifeprex and its April 11, 2019, approval of Mifepristone Tablets, 200 mg, and remove them from the list of approved drugs;
- 2) Withdraw or suspend its March 29, 2016, Approval of Danco Laboratories, LLC's supplemental new drug application for Mifeprex (Application Number: 020687Orig1s020); and
- 3) Withdraw or suspend its April 12, 2021, Non-Enforcement Decision letter, and December 16, 2021, Response to the 2019 Citizen Petition concerning the in-person dispensing requirement for mifepristone.

It is FURTHER ORDERED that Defendants, and their officials, agents, employees, and all persons in active concert or participation with them, including

their successors in office, are enjoined from enforcing the Federal Food, Drug, and Cosmetic Act inconsistent with these orders while they remain in effect.

Because this case serves the public interest, no bond or other security is required.

SO ORDERED.

Dated _____	_____ MATTHEW J. KACSMARYK UNITED STATES DISTRICT JUDGE
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